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Re-evaluation Decision

RVD2014-06

Paclobutrazol

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Re-evaluation Decision

Paclobutrazol is a plant growth regulator. Five paclobutrazol products are currently registered in Canada under the authority of the *Pest Control Products Act*, including two technical grade active ingredients, two commercial class end-use products and one manufacturing concentrate.

Following a re-evaluation of paclobutrazol, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration of products containing paclobutrazol for sale and use in Canada. An evaluation of available scientific information found that products containing paclobutrazol do not present unacceptable risks to human health or the environment when used according to the conditions of registration, which include amended label directions. Paclobutrazol was also found to have value as a plant growth regulator. As a condition of the continued registration of paclobutrazol, label amendments are required for all end-use products. Appendix I lists the required label amendments. No additional data are being requested at this time.

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, Re-evaluation Program Cyclical Re-evaluation, presents the details of the cyclical re-evaluation approach, which is in line with the requirements of the *Pest Control Products Act*. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

This re-evaluation decision¹ was proposed in the consultation document, Proposed Re-evaluation Decision PRVD2013-04, *Paclobutrazol*, which describes the decision-making stage of the PMRA's regulatory process and summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. Therefore, this decision is consistent with the decision proposed in PRVD2013-04. Please refer to PRVD2013-04 for both the 'Overview' of the re-evaluation decision and the detailed 'Science Evaluation' of the human health, environmental and value considerations underlying the re-evaluation decision. A reference list for all data used as the basis for the re-evaluation decision is also included in PRVD2013-04.

To comply with this decision, registrants of paclobutrazol products will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

¹ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection² regarding this decision on paclobutrazol within 60 days from the date of publication of this Re-evaluation Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

² As per subsection 35(1) of the Pest Control Products Act

Appendix I Label Amendments for End-Use Products Containing Paclobutrazol

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of commercial end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in a section entitled **PRECAUTIONS**.

Wear chemical-resistant coveralls over a long-sleeved shirt and long pants, and chemical-resistant gloves during mixing, loading, application, cleanup and repair activities.

II) It is recommended that the current label requirement for applicators to wear a NIOSH-approved respirator during application be removed from end-use product labels.

III) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.